Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network

Voluntary Report - public distribution

Date: 9/26/2002

GAIN Report #EC2009

Ecuador

Sanitary/Phytosanitary/Food Safety

Sanitary Registration for Food Products

2002

Approved by:
Lawrence D. Fuell, AgAttache
U.S. Embassy Quito
Prepared by:
Rene A. Alarcon, Marketing Specialist

Report Highlights:
Ecuador passed a new Health Law in 2000. In june of 2001, Application Rules for issuance of Sanitary Registrations for food products were released. To some extent, these rules have improved the registration process. However, problems remain because several core parts of the new rules have not been implemented by Ecuadorian Sanitary Authoritie due to a variety of reasons.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Lima [PE1], EC

BACKGROUND

The "Ley de Promoción Social y Participación Ciudadana, Segunda Parte" (Trolley Bus II law) was issued by the Government of Ecuador (GOE) in August of 2000. This law contained significant reforms to the issuance process of sanitary permits for food products. Application rules for this new law had been under discussion and pending since January of 2001.

On June 18th, 2001, the GOE released the Official Register number 349, containing new Application Rules for Sanitary Permit Issuance and Sanitary Control (Hereafter "Application Rules"). This document describes the overall process and requirements for the issuance of a Sanitary Registrations (SR) for locally produced, as well as imported food and beverage products. These important and long-expected reforms were expected to significantly ease import procedures for food products.

THE NEW LAW

Principal changes contained in the Application Rules are those relating to terms of issuance, equal treatment, free sale certificates validation, expiration terms, and a decentralization of the process, which has been being managed by the National Institute of Hygiene Izquieta Perez (INHIP) located in Guayaquil. The following table summarizes how the new legislation changes the process:

SUBJECT	BEFORE	NOW
Time for issuing the SP	6 months to 1.5 years	30 days
Expiration term	7 years	10 years
Analysis made by	INHIP	No laboratory analysis for imported products*
Administrative process	INHIP in Guayaquil	IHNIP in Guayaquil, Quito or Cuenca.
Equal treatment	No	Accept Free Sale Certificate extended to products in country of origin.

The National System of Surveillance and Control comprised by the Ministry of Health, and other health control agencies is the entity responsible for implementing the new rules.

According to sanitary authorities, the new rules are designed to put an end to decades of centralization and inefficiency at the National Institute of Hygiene Izquieta Perez (INHIP), based in Guayaquil. This agency had a monopoly over issuance of sanitary permits for over fifty years. As such, these rules represent an important first step in expanding fair trade practices in Ecuador. Some of the improvements that are expected to be maintained, added, and reinforced by the new rules are as

follows:

- Foreign countries' free sale and good manufacturing practice certificates are being accepted as legal documents for registering imported products depending on the country, and given the case that such country has been included in a list to be released by the President of the Republic.

- Sanitary permits will be issued in terms thirty (30) days, or less.

- Improvements will be made in the renewal process for sanitary permits specifically regarding the number of required documents to obtain such renewal.

- Product analysis made by competent institutions in the country of origin or a certified laboratory would be accepted in lieu of testing by Ecuadorian laboratories.

CURRENT SITUATION

One year after the publication of new rules for issuance of food product registrations, Ecuadorian importers, as well as U.S. exporters continue to face difficulties in the process of obtaining sanitary permits for processed food products.

Part of the problem stands on a dispute between the Ministry of Health's main offices in Quito and a branch of the Izquieta Perez Institute (the sanitary control agency of this Ministry) located in Guayaquil. Historically, only this branch in Guayaquil handled product registrations, including technical analysis, and the administrative process. As the new law mandates, product registration requests can now be filed in two other branches of the same institute, located in Quito and Cuenca. This decision runs counter to this institute's practice over the last fifty years, and has received opposition from its directing officials. Guayaquil's Izquieta Perez refuses to comply with the new rules; therefore, this branch continues to carry out laboratory analysis, and requests documents not included as requirements by the Application Rules released in June of 2001.

In addition, Ecuador's new Health Code (supreme law governing sanitary activities in the country) seems to contradict itself in two of its most important articles in reference to the issuance of sanitary registrations through "Equal Treatment" or "Homologation". Article 105 explicitly states that the only condition for an imported food product to receive a sanitary registration -by equal treatment- is that such product has previously been granted a free sale certificate, or a good manufacturing practice certificate in the country of origin. On the other hand, article 106 of the Health Code establishes that the sanitary registration will be granted by homologation only if it has not been justifiably denied within thirty (30) days after the application has been filed. In summary, article 106 rules that homologation will only be applicable if after thirty days of the application date, the sanitary registration has not been denied.

As an example, suppose Company A is interested in registering a product described as X canned tomato sauce. Ecuadorian authorities will require for Company A to deliver several documents

described in the Aplication Rules (and below herein, among others). According to article 105 of the Health Code, the regular process -being currently applied- determines that X canned tomato paste, after complying with all requirements, will be granted a sanitary registration -by homologation- in a term no longer than thirty (30) days. However, article 106 of this very same law states that only if the sanitary registration has been denied (after the thirty-day term, based on scientific justification), it will be understood as granted by homologation. What is more, the Aplication Rules released in June of 2001, determine that the unique applicable process for registering imported products is homologation. This incongruence may provoke difficulties within the Ministry of Health, where sanitary officials would be perfectly free to apply either article 105 or 106 of the law, or those in the Application Rules to deny issuance of sanitary registrations to the detriment of imported products.

Last but not least, bigger problems stand in several documents required by Ecuadorian sanitary authorities for issuance of sanitary registrations. Principal requirements, either causing or not problems to U.S. exports, include:

1. **Free Sale Certificate** (FSC), required to be issued by a competent health authority in your state or country. To our knowledge, the Health Services Department in every state in the U.S. is able to issue this certificate. Copies of this certificate are not accepted, only originals, and the documents must include a list of the products being covered by it.

2. **The Quali-Quantitative (composition) Formula**.

   This is a mandatory requirement in order to register any food product for sale in Ecuador. All foreign companies, whether they produce dairy, wine, cereal, beverages, etc., are required to declare product formulation for sanitary registration. This document(s) will declare the product name, and must show percentages in decreasing order of the product's ingredient list presented in the label for each product. Range formulas are not accepted.

   Ecuadorian authorities explain the existence of this document by the fact that imported products are not subject to laboratory analysis prior to registration. Therefore, the composition list provided by the exporter will serve as a baseline (and a legal document) for further sanitary control. Were a consumer harmed by an imported product, sanitary authorities will take samples from the market for analysis. The results of such analysis will be compared to the product's declared composition, and could be the basis of legal action.

   Some applicants feel reluctant to complying with this requirement, mainly because they do not feel confident enough about sharing their composition formulas. However, this is a requirement applied for all products to be registered, including locally produced as well as imported products. Also, all applicants must deliver such information for obtaining a sanitary registration for their products. According to local health authorities, this information is kept with the highest confidentiality in order to avoid deviation of secret formulas, and further illicit copying of products. Documents must be original, no copies accepted. Documents must also be signed by the company's food technician, and one should be issued for each item to be exported.

3. Product Analysis Certificate

This document refers to a quality certificate for the product, which contains data corresponding to results of a laboratory analysis. This certificate can be issued by any competent authority in the food industry, or the company itself when its laboratories have been authorized by a competent U.S. health authority. For example, in Argentina, the Instituto Nacional de Vitivinicultura (National Wine Institute) is authorized to conduct quality analyses for wine. As result, they issue a "certificate of analysis" declaring product name, manufacturer, alcoholic content, PH, density, acid content, sugars, flavor, aroma, color, ashes, among other things.

4. Manufacture Process Declaration

This document is not included in the official list of requirements specified in the Application Rules. However, local sanitary authorities require a brief declaration of the manufacture process for the products to be registered. Other countries, including the U.S. have questioned the legitimacy of this additional requirement, claiming that it is not included in the Application Rules. Government officials at the Ministry of Health of Ecuador also do not seem to find an adequate, scientific justification for maintaining this requirement.

SUGGESTIONS AND COMMENTS

Although the Government of Ecuador has taken a first step towards the modernization of internal processes for the issuance of sanitary registrations for both locally produced and imported food products, several changes have not yet been implemented. The jurisdictional dispute between branches of the Izquieta Perez Institute makes it difficult for importers to have their products registered, as well as for government officials to implement the changes proposed by the Application Rules.

Lack of resources limits the possibility of automating the process. Most administrative processes, such as filing, follow up, communications and information management continue to be physical, not electronic. Modernization of systems is urgently needed for Izquieta Perez to be able to guarantee confidentiality over sensitive product information provided by multinational companies.

Furthermore, several inconsistencies in the law itself leave open the door for different interpretations by sanitary authorities, as well as by importers, and final users. Inefficiencies by government institutions in charge of releasing sub-rules to clarify outstanding gaps between the application rules and the Health Code, turn Application Rules' enforcement into a more difficult duty.

Temporary solutions have been suggested by Ecuador's sanitary authorities, among which it is strongly encouraged that U.S. exporters, and their local representatives file the documents themselves, without the use of intermediaries, such as law firms. According to government officials, some intermediaries delay the process for their own benefit, and even modify documents without the authorization of the

product's manufacturer, making more difficult for local authorities to trust in the truthfulness of the information provided, specifically regarding composition formulas and manufacture process. Also, as a temporary solution to the outstanding internal dispute at the Izquieta Perez, it is highly recommended by local authorities that applications are filed at the Izquieta Perez Institute in Quito, rather than in Guayaquil.

FURTHER INFORMATION

Should you have any questions or need further assistance, such as an informal translation into English of the Application Rules, please contact:

Foreign Agricultural Service
U.S. Department of Agriculture
United States Embassy-Quito
Av. Colombia 1573 y Queseras del Medio
Piso 3
Quito, Ecuador
Phone: 593-2-252-9088 / 256-4147
FAX:593-2-250-6283 / 250-4888
E-mail: Agquito@fas.usda.gov
Internet: www.fas-la.org/Ecuador